DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

January 24, 2007

2007-DAL-WL-7

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Thomas L. Crofut, Owner
and Mrs. Judith H. Crofut, Owner
Good Flow Juice Company
2601 East Cesar Chavez Street
Austin, Texas 78702

Dear Mr. and Mrs. Crofut:

The Food and Drug Administration inspected your juice processing facility, located at 2601 East Cesar Chavez Street, Austin, Texas, on August 28-31 and September 1-7, 2006, and found that you have serious deviations from the juice Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 120, and the Current Good Manufacturing Practice regulation for foods, Title 21, Code of Federal Regulations, Part 110 (21 CFR Parts 120 & 110). In accordance with 21 CFR 120.9, failure of a processor of juice products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 120, renders the juice products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your fresh unpasteurized juices from oranges, grapefruits, limes, lemons, watermelons, bananas, strawberries, pineapples, and their juice blends are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the juice HACCP regulation, and the Juice HACCP Hazards and Controls Guidance through links in FDA's home page at www.fda.gov.

Your significant violations were as follows:

1. You must include in your HACCP plan control measures that will consistently produce, at a minimum, a 5 log reduction, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism, to comply with 21 CFR 120.24(a). However, the control measures listed in your HACCP plan are not adequate to achieve such a reduction.

We note in your letter dated September 12, 2006 that you request exemption from the 5 log reduction requirement. All juice processors (except retail establishments as defined in the regulation) must comply with the juice processing regulation for each type of juice they produce. A processor that sells or distributes juice to other business entities is not a retail establishment (21 CFR 120.3(l)). Because your firm sells juice wholesale, it does not qualify as a retail establishment and is subject to the juice processing regulation. You may find further discussion regarding retail establishments in guidance on FDA's web site.

2. You must monitor conditions and practices during processing with sufficient frequency to ensure conformance with current good manufacturing practice regulations, to comply with 21 CFR 120.6(b). However, your firm did not monitor prevention of cross-contamination from insanitary objects with sufficient frequency, as evidenced by:

i. Employees were observed transferring whole citrus fruits such as oranges, grapefruits, lemons, and limes from shipping cases onto the processing table without washing or rinsing. These citrus fruits were then sliced into two halves, placed into tubs containing tap water, and subsequently juiced by hand.

ii. An employee was observed picking up a tub of oranges from the floor and setting the tub on the corner of a cutting board. Subsequently, the cutting board was used to slice oranges that were then processed into finished, fresh juice.

iii. An employee was observed retrieving a whole orange that had fallen on the floor and returning it to a pile of oranges on the processing table. These oranges were processed into finished juice without further washing and sanitization.

iv. An employee was observed picking up a grapefruit half from the wet floor and then resuming the manual juicing operation without changing gloves. This same employee, within 10 minutes, picked up a lemon half from the wet floor and resumed manual juicing operations without changing gloves.

3. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 120.6(c). However, your firm did not maintain sanitation control records for the safety of water; the condition of all food contact surfaces; the prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces, and from raw product to processed product; the protection of food, food packaging materials, and food contact surfaces from adulteration with contaminants; proper labeling, storage, and use of toxic compounds; and exclusion of pests.

We acknowledge the receipt of your letter dated September 12, 2007. We may take further action if you do not promptly correct these violations. For instance, we may initiate

regulatory action without further informal notice. Such actions may include the initiation of a seizure action against your products and/or an action to enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as copies of your revised juice HACCP plans; process controls for 5 log reduction of pertinent microorganisms; sanitation monitoring records; related sanitation corrective actions; or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the juice HACCP regulation and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Carolyn A. Pinney, Compliance Officer, at the above letterhead address. If you have any questions regarding any issue in the letter, please contact Carolyn A. Pinney at (214) 253-5220.

Sincerely,

Michael A. Chappell
Dallas District Director

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